

## **REMARKS**

After entry of this amendment, claims 1-131 and 192-273 will be pending. Applicants believe that no new matter has been introduced by the above amendments. As the application has already published as United States Patent Application Publication No. US 2004/0106625 A1 on June 3, 2004, Applicants believe the submission of a substitute specification containing the current amendments is not required.

The specification has been amended to correct typographical and/or clerical errors. Specifically, on page 52, line 5, the misprint of "(R)-configuration" has been corrected to "(S)-configuration". Support for this amendment may be found, *inter alia*, in Compounds BQO(b) through BSD(b) on pages 123-125 of Table 4 and Compounds CCK(b) through CDZ(b) on pages 135-137 of Table 5. On page 169, line 5, the misprint of "-(C<sub>3</sub>-C<sub>7</sub>)heterocycle" has been corrected to "-(C<sub>3</sub>-C<sub>5</sub>)heterocycle".

Claims 1, 19, 21-23, 41, 42, 60, 62-64, 82-84, 100 and 101 have been amended to correct typographical and/or clerical errors. New claims 237-273 have been added. Claims 132-191 have been canceled without prejudice solely to expedite the allowance of the remaining claims. Applicants expressly reserve the right to file one or more continuation and/or divisional applications directed to the subject matter of the canceled claims and/or subject matter of the present amendments.

Support for the new claims may be found, *inter alia*, at the location(s) in the initially filed specification and claims as indicated below:

<b>CLAIM NO.</b>	<b>EXEMPLARY SUPPORT</b>
New claim 237	Page 65, line 25 of the specification; original claim 83
New claims 238 and 239	Page 45, lines 15 and 18; Compounds AAA through AFJ in Table 1 on pp. 81-86 of the specification
New claims 240-242 and 248-250	Compounds AAA-AAC, AAM-AAG, ABA-ABE, ABO and ABP in Table 1 on pp. 81-82 of the specification; original claims 6-8
New claims 243, 244, 251 and 252	Compounds AAG, AAU and ABI in Table 1 on pp. 81-82 of the specification
New claims 245, 246, 253 and 254	Compounds AAI, AAW and ABK in Table 1 on pp. 81-82 of the specification
New claims 247 and 265	Page 45, lines 22 and 26 of the specification
New claims 255-257	Page 45, lines 15 and 19; page 46, line 14; Compounds BJO through BOX in Table 4 on pp. 117-122; Compounds BVK through CAT in Table 5 on pp. 129-134 of the specification

CLAIM NO.	EXEMPLARY SUPPORT
New claims 258-260 and 266-268	Compounds BJO-BJQ, BKA-BKE, BKO-BKS, BLC and BLD in Table 4 on pp. 117-118; Compounds BVK-BVM, BVW-BWA, BWK-BWO, BWY and BWZ in Table 5 on pp. 129-130 of the specification; original claims 6-8
New claims 261, 262, 269 and 270	Compounds BJU, BKI and BKW in Table 4 on pp. 117-118; Compounds BVQ, BWE and BWS in Table 5 on pp. 129-130 of the specification
New claims 263, 264, 271 and 272	Compounds BJW, BKK and BKY in Table 4 on pp. 117-118; Compounds BVS, BWG and BWU in Table 5 on pp. 129-130 of the specification
New claim 273	Compound BJU in Table 4 on page 117; Compound BVQ in Table 5 on page 129 of the specification

### **The Restriction Requirement**

In the Office communication of December 27, 2005, a Restriction Requirement was imposed under 35 U.S.C. § 121 requiring election of one of 28 groups and the election of a specifically disclosed species to be examined for search purposes.

Thereafter, a telephonic discussion was held between Applicants' representative George A. Senich, Reg. No. 42,140, and Examiner Paul V. Ward on March 9, 2006 ("interview") to clarify certain issues in connection with the Restriction Requirement for the above-identified application, thereby advancing the prosecution of the application, and not to discuss the patentability of the pending application. Applicants are grateful for the courtesies extended by Examiner Ward. During the interview, Mr. Senich discussed the status of claims 1-236. Pursuant to MPEP § 713.04, Applicants submitted the statement of the substance of the Applicants-initiated interview within the remarks of the AMENDMENT AND PROVISIONAL ELECTION UNDER 37 C.F.R. § 1.143 WITH TRAVERSE AND STATEMENT OF THE SUBSTANCE OF THE INTERVIEW filed on March 22, 2006 ("Amendment/Election/Interview"). That Amendment/Election/Interview appears to have been received, as its first page was date-stamped March 22, 2006 in its upper left corner (see Exhibit A hereto) and it is itemized as "03-22-2006 Response to Election / Restriction Filed" in the Transaction History of the above-identified application (see Exhibit B hereto with this item emphasized); however, the amendments to the claims made therein, e.g., canceling claims 132-191 without prejudice, appear **NOT** to have been entered, as, *inter alia*, the "Office Action Summary" page of the July 11, 2006 Office communication indicates that

"claim(s) 1-236 is/are pending in the application."

Therefore, pursuant to 37 C.F.R. §§ 1.115(b)(1) and 1.121, Applicants respectfully request entry of the amendments to the specification and claims present in this paper, which merely repeat the amendments to the specification and claims present in the previously-filed Amendment/Election/Interview.

In the July 11, 2006 Office communication, a Restriction Requirement was imposed under 35 U.S.C. § 121 as follows, requiring election of one of the following groups for prosecution on the merits, each of which is alleged to encompass a separate invention:

- I. Compounds and compositions according to claims 1-22, of Formula I, classified in class 546, various subclasses;
- II. Compounds and compositions according to claims 23-41, of Formula II, classified in class 544, various subclasses;
- III. Compounds and compositions according to claims 42-63, of Formula III, classified in class 544, subclass 242;
- IV. Compounds and compositions according to claims 64-82, of Formula IV, classified in class 544, subclass 233;
- V. Compounds and compositions according to claims 83-99, of Formula V, classified in class 548, subclass 100+;
- VI. Compounds and compositions according to claim 100, of Formula VI, classified in classes 544 or 548, various subclasses;
- VII. Compounds and compositions according to claim 101, of Formula VII, classified in class 544 or 548, various subclasses;
- VIII. Methods of treating according to claims 117-206 that relate to Formula I, classified in class 514;
- IX. Methods of treating according to claims 117-206 that relate to Formula II, classified in class 514;
- X. Methods of treating according to claims 117-206 that relate to Formula III, classified in class 514;
- XI. Methods of treating according to claims 117-206 that relate to Formula IV, classified in class 514;
- XII. Methods of treating according to claims 117-206 that relate to Formula V, classified in class 514;

- XIII. Methods of treating according to claims 117-206 that relate to Formula VI, classified in class 514;
- XIV. Methods of treating according to claims 117-206 that relate to Formula VII, classified in class 514;
- XV. Methods of preparing according to claims 222-236 that relate to Formula I, classified in classes 544 and 548;
- XVI. Methods of preparing according to claims 222-236 that relate to Formula II, classified in classes 544 and 548;
- XVII. Methods of preparing according to claims 222-236 that relate to Formula III, classified in classes 544 and 548;
- XVIII. Methods of preparing according to claims 222-236 that relate to Formula IV, classified in classes 544 and 548;
- XIX. Methods of preparing according to claims 222-236 that relate to Formula V, classified in classes 544 and 548;
- XX. Methods of preparing according to claims 222-236 that relate to Formula VI, classified in classes 544 and 548;
- XXI. Methods of preparing according to claims 222-236 that relate to Formula VIII (*sic*), classified in classes 544 and 548;
- XXII. Kits according to claims 207-210 of Formula I, classified in class 206, subclass 569;
- XXIII. Kits according to claims 211-212 of Formula II, classified in class 206, subclass 569;
- XXIV. Kits according to claims 213-216 of Formula III, classified in class 206, subclass 569;
- XXV. Kits according to claims 217-218 of Formula IV, classified in class 206, subclass 569;
- XXVI. Kits according to claims 219 of Formula V, classified in class 206, subclass 569;
- XXVII. Kits according to claims 220 of Formula VI, classified in class 206, subclass 569; and
- XXVIII. Kits according to claims 221 of Formula VII, classified in class 206, subclass 569.

**Requests for Further Clarification**

1. Applicants note that certain claims, i.e., pending dependent

"composition" claims 102-116, have not been assigned to any of the above groups. However, as the July 11, 2006 Office communication states, on page 4, that the "composition claims will be examined along with each elected compound group, respectively," Applicants believe that each of these claims is related to the following Groups:

Claim 102 (Formula I)	Group I
Claim 103 (Formula Ia)	Group I
Claim 104 (Formula Ib)	Group I
Claim 105 (Formula Ic)	Group I
Claim 106 (Formula II)	Group II
Claim 107 (Formula IIa)	Group II
Claim 108 (Formula III)	Group III
Claim 109 (Formula IIIa)	Group III
Claim 110 (Formula IIIb)	Group III
Claim 111 (Formula IIIc)	Group III
Claim 112 (Formula IV)	Group IV
Claim 113 (Formula IVa)	Group IV
Claim 114 (Formula V)	Group V
Claim 115 (Formula VI)	Group VI
Claim 116 (Formula VII)	Group VII

Therefore, Applicants respectfully request written clarification of the status of claims 102-116 in the next communication from the Office.

2. Applicants note that Group XXI is said to relate to Formula VIII; however, there is no Formula VIII in the application. Applicants believe this is a typographical error and that Group XXI is meant to relate to Formula VII, the next formula in the series after Group XX to which Formula VI relates. However, Applicants respectfully request written clarification in the next communication from the Office.

### **Traverse of the Restriction Requirement**

Applicants respectfully traverse the Restriction Requirement.

Specifically, Applicants request that the requirement be modified to the extent that:

- the groups encompassing Formulae VI and VII, e.g., Groups VI and VII, be combined and examined together,
- Groups VIII through XIV be combined and examined together,
- Groups XV through XXI be combined and examined together, and
- Groups XXII through XXVIII be combined and examined together

in the above-identified application. For the reasons provided below, Applicants submit that the subject matter of these claims merits combined examination.

In particular, Applicants submit that a search of the art for the compounds of Formula VII having a link comprising three carbon atoms between the amine nitrogen atom and Ar<sub>2</sub>, as recited in independent claim 101, will also likely yield the prior art, if any, for the compounds of Formula VI having a link comprising two carbon atoms between the amine nitrogen atom and Ar<sub>2</sub>, as recited in independent claim 100. That is, a search of the prior art for the subject matter of Group VII, viz the compounds of Formula VII, would encompass not only art disclosing such compounds but also art disclosing the compounds of Formula VI. Applicants further note that, for the compounds and compositions presently classified into Groups VI and VII, each group is classified into the same classes -- classes 544 and 548. Therefore, Applicants respectfully submit that, as any art identified in a search by the Examiner for the compounds of Group VII will likely also encompass the compounds of Formula VI, under M.P.E.P. § 803 the subject matter of Group VII and Formula VI can be examined together in a single application without imposing a serious burden on the Examiner. The M.P.E.P. § 803 (Eighth Edition, Revision 3, August 2005) provides that:

If the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.

As Applicants understand it from the interview, the Examiner agreed to combine Groups VI and VII for this reason and examine the combination; however, that combination is not reflected in the July 11, 2006 Office communication. Applicants respectfully request written clarification in the next communication from the Office. For the same reasons, claim 115 ("composition claim for Formula VI") and claim 116 ("composition claim for Formula VII") can be examined together, as can:

- claims 130 and 205 (Group XIII) and claims 131 and 206 (Group XIV);
- claims 235 (Group XX) and claims 236 (Group XXI); and
- claims 220 (Group XXVII) and claims 221 (Group XXVIII).

Applicants note that for the "methods of treating," presently classified into Groups VIII through XIV, each group is classified into the same class -- class 514. Thus, a search of the prior art for the subject matter of, e.g., Group VIII, *viz* the compounds of Formula I, would encompass not only art disclosing such methods but also art disclosing the methods of Groups IX through XIV. Therefore, Applicants respectfully submit that any art identified in a search by the Examiner for the methods of Group VIII will necessarily encompass the methods of Groups IX through XIV. Applicants further submit that, under M.P.E.P. § 803, the subject matter of claims 117-131 and 192-206 (claims 132-191 having been canceled without prejudice) can be examined together in a single application without imposing a serious burden on the Examiner.

Moreover, Applicants note that for the "methods of preparing," presently classified into Groups XV through XXI, each group is classified into the same two classes -- classes 544 and 548. Thus, a search of the prior art for the subject matter of, e.g., Group XV, *viz* the compounds of Formula I, would encompass not only art disclosing such methods but also art disclosing the methods of Groups XVI through XXI. Therefore, Applicants respectfully submit that any art identified in a search by the Examiner for the methods of

Group XV will necessarily encompass the methods of Groups XVI through XXI. Thus, under M.P.E.P. § 803, the subject matter of claims 222-236 can be examined together in a single application without imposing a serious burden on the Examiner.

Applicants also note that for the "kits," presently classified into Groups XXII through XXVIII, each group is classified into the same class and the same subclass -- class 206, subclass 569. Thus, a search of the prior art for the subject matter of, e.g., Group XXII, viz a kit comprising the compounds of Formula I, would encompass not only art disclosing such kits but also art disclosing kits comprising compounds of Formulas II through VII, i.e., Groups XXIII through XXVIII. Therefore, Applicants respectfully submit that any art identified in a search by the Examiner for the kits of Group XXII will necessarily encompass the kits of Groups XXIII through XXVIII. Thus, under M.P.E.P. § 803, the subject matter of claims 207-221 can be examined together in a single application without imposing a serious burden on the Examiner.

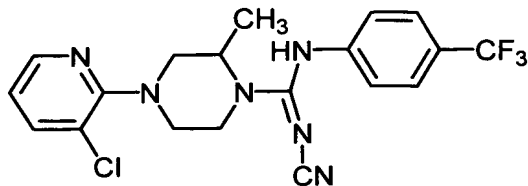
Applicants note that, as the Office communication states on page 5 that "a search of the four groups designated above would impose ..." (emphasis added), perhaps it is already contemplated that Groups I through VII be combined into one "master group 1," Groups VIII through XIV be combined into one "master group 2," Groups XV through XXI be combined into one "master group 3," and Groups XXII through XXVIII be combined into one "master group 4".

Accordingly, pursuant to the above remarks, Applicants respectfully request that the Restriction Requirement under 35 U.S.C. § 121 be reconsidered and revised.

### **Provisional Election**

However, in order to be fully responsive to the outstanding Restriction Requirement, Applicants hereby provisionally elect, with traverse, as the specifically disclosed species of the invention to be examined for search purposes (as requested on page 5 of the Office communication), Compound BVQ (see Table 5, page 129, line 21 of the specification), i.e.:





**Compound BVQ**

Applicants note that claim 21, reciting Formula Ib, claims 104, 119, 194, 209 and 224, and new claims 255-257, 261, 262, 265, 269, 270 and 273 read on Compound BVQ. *Inter alia*, claim 21 is believed to be generic. As the July 11, 2006 Office communication assigns claim 21 to Group I, Applicants provisionally elect, with traverse, Group I which includes claim 21.

These provisional elections are made without prejudice to Applicants' right to pursue the non-elected subject matter in one or more related applications.

Attorneys for Applicants retain the right to petition from this Restriction Requirement under 37 C.F.R. § 1.144.

Applicants respectfully request that the present statement be entered and made of record in the above-identified patent application.

No fee is believed to be due for this response. Should any fee be required, please charge such fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

*Samuel B. Abrams by  
Heng G. Sun 42,140*

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Samuel B. Abrams (Reg. No. 30,605)

**JONES DAY**  
222 East 41st Street  
New York, New York 10017  
(212) 326-3939

Enclosures